

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:**  
**Stryker® Leibinger Skeletal Anchoring System**

**General Information**

K041651

Proprietary Name: Stryker® Leibinger Skeletal Anchoring System  
Common Name: Endosseous Implant  
Proposed Regulatory Class: Class III  
Device Classification: DZE (872.3640)  
Submitter: Stryker Leibinger  
4100 East Milham Avenue  
Kalamazoo, MI 49001  
269-323-4226  
Submitter's Registration #: 1811755  
Manufacturer's Registration #: 8010177  
Contact Person: Wade T. Rutkoskie  
Associate Manager RA QA  
Phone: 269-323-4226  
Fax: 269-323-4215  
Summary Preparation Date: June 4, 2004

**Intended Use**

The Stryker® Leibinger Universal Skeletal Anchoring System is a plating system intended to be placed in the mouth for use as an anchor in orthodontic procedures.

**Substantial Equivalency Information**

The Stryker® Leibinger Skeletal Anchoring System is substantially equivalent to legally marketed K033483 KLS-Martin Ortho Anchorage System, K022185 Universal CMF System.



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

SEP 30 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Wade T. Rutkoskie  
Regulatory Affairs Associate  
Stryker Instruments  
4100 East Milham Avenue  
Kalamazoo, Michigan 49024

Re: K041651

Trade/Device Name: Stryker Leibinger Skeletal Anchoring System  
Regulation Number: 872.3640  
Regulation Name: Endosseous Implant  
Regulatory Class: II  
Product Code: DZE  
Dated: September 21, 2004  
Received: September 23, 2004

Dear Mr. Rutkoskie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

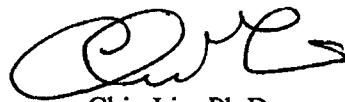
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address  
<http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K041651

Device Name: Stryker Leibinger Skeletal Anchoring System

Indications For Use:

The Stryker Leibinger Skeletal Anchoring System is a plating system intended to be placed in the mouth, for use as an anchor in orthodontic procedures.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF  
NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Robert R. Roberts for Dr. Susan Runner*  
(Division Sign-Off)

Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

Page 1 of 1

510(k) Number: K041651